

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
McALLEN DIVISION**

**MARIA ELOISA VILLARREAL,
Individually and as Administrator a/n/f
Of the Estate of JULIO VILLARREAL,
SR., Deceased
Plaintiff,**

V.

TARO PHARMACEUTICALS USA, INC.

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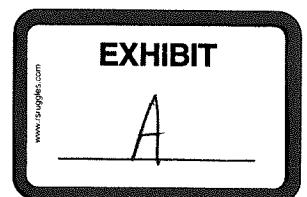
CIVIL ACTION NO. 7:17-cv-35

**TARO PHARMACEUTICALS USA, INC.'S
FIRST AMENDED ANSWER TO PLAINTIFF'S AMENDED COMPLAINT**

TO THE HONORABLE UNITED STATES DISTRICT JUDGE OF SAID COURT:

COMES NOW DEFENDANT, TARO PHARMACEUTICALS USA, INC. in the above numbered and entitled cause and files its First Amended Answer to Plaintiff's Amended Complaint as follows:

1. Defendant is without knowledge or information sufficient to form a belief as to the truth of the averments as to Plaintiff's personal information or consumption of medications, but denies that it negligently designed, manufactured or marketed any defected product that caused or contributed to the alleged injury or damages claimed by Plaintiff.
2. Defendant is without knowledge or information sufficient to form a belief as to the truth of the averments as to Plaintiff's personal information or consumption of medications, but denies that it negligently designed, manufactured or marketed any defected product that caused or contributed to the alleged injury or damages claimed by Plaintiff.



3. Defendant admits it manufactures and distributes medication named or similar to Amiodarone, is without knowledge or information sufficient to form a belief as to the truth of the allegations of Plaintiff's consumption, denies that it directly provided any product to Plaintiff, denies that it failed to provide any applicable warnings, if any, and denies that it negligently designed, manufactured or marketed any defected product that caused or contributed to the alleged injury or damages claimed by Plaintiff.

4. Defendant is without knowledge or information sufficient to form a belief as to the allegations of Plaintiff's diagnosis or health status.

5. Defendant denies the allegations set forth in this paragraph.

6. Defendant denies the allegations set forth in this paragraph.

7. Defendant admits that Wyeth has obtained various government approvals for the manufacture and sale of amiodarone and denies Plaintiff's claims as to specific medication use and approvals obtained by Wyeth.

8. Defendant denies the allegations set forth in this paragraph.

9. Defendant denies the allegations set forth in this paragraph.

10. Defendant denies the allegations set forth in this paragraph.

11. Defendant denies the allegations set forth in this paragraph.

12. Defendant denies the allegations set forth in this paragraph.

13. Defendant denies the allegations set forth in this paragraph.

14. Defendant denies the allegations set forth in this paragraph.

15. Defendant is without knowledge or information sufficient to form a belief as to the truth of the averments as to Plaintiff's personal information.

16. Defendant is without knowledge or information sufficient to form a belief as to the truth of the averments as to Plaintiff's personal information.

17. Defendant denies that it is a New York corporation with its principal place of business in New York, New York and would show that it is a New Jersey corporation with its principal place of business in Pennington, Pennsylvania. Defendant admits that it conducts business throughout the United States, and that it manufactures and markets amiodarone. Defendant is without knowledge or information sufficient to form a belief as to the truth of Plaintiff's assertions as to purchase of medications.

18. Defendant specially excepts to the allegations of this paragraph for the reason that they are too vague and ambiguous to allow Defendant to admit or deny same.

19. Defendant specially excepts to the allegations of this paragraph for the reason that they are too vague and ambiguous to allow Defendant to admit or deny same.

20. Defendant is not contesting venue in this matter.

21. Defendant admits the averments of this paragraph.

22. Defendant is without knowledge or information sufficient to form a belief as to the allegations in connection with Wyeth's FDA approval process or specific timing and results.

23. Defendant is without knowledge or information sufficient to form a belief as to the allegations in connection with Wyeth's FDA approval process or specific timing and results.

24. Defendant is without knowledge or information sufficient to form a belief as to the allegations in connection with Wyeth's FDA approval process or specific timing and results. Defendant denies the remaining allegations of this paragraph.

25. Defendant is without knowledge or information sufficient to form a belief as to the allegations in connection with Wyeth's FDA approval process or specific timing and results. Defendant denies the remaining allegations of this paragraph.

26. Defendant is without knowledge or information sufficient to form a belief as to the truth of the averments as to Plaintiff's personal information and denies the remaining allegations of this paragraph.

27. Defendant is without knowledge or information sufficient to form a belief as to the truth of the averments as to Plaintiff's personal information.

28. Defendant is without knowledge or information sufficient to form a belief as to the truth of the averments as to Plaintiff's personal information and denies the remaining allegations of this paragraph.

29. Defendant is without knowledge or information sufficient to form a belief as to the truth of the averments as to Plaintiff's personal information and denies the remaining allegations of this paragraph.

30. Defendant denies the allegations set forth in this paragraph.

31. Defendant denies the allegations set forth in this paragraph.

32. Defendant denies the allegations set forth in this paragraph.

33. Defendant denies the allegations set forth in this paragraph.

34. Defendant denies the allegations set forth in this paragraph.

35. Defendant denies the allegations set forth in this paragraph.

36. Defendant is without knowledge or information sufficient to form a belief as to the truth of the averments as to Plaintiff's personal information.

37. Defendant is without knowledge or information sufficient to form a belief as to the truth of the averments as to Plaintiff's personal information.

38. Defendant is without knowledge or information sufficient to form a belief as to the truth of the averments as to Plaintiff's personal information.

39. Defendant denies the allegations set forth in this paragraph.

40. Defendant specially excepts to the allegations of this paragraph for the reason that they are too vague and ambiguous to allow Defendant to admit or deny same.

41. Defendant specially excepts to the allegations of this paragraph for the reason that they are too vague and ambiguous to allow Defendant to admit or deny same.

42. Defendant specially excepts to the allegations of this paragraph for the reason that they are too vague and ambiguous to allow Defendant to admit or deny same. Subject to and without waiving this objection, Defendant denies the allegation set forth in this paragraph.

43. Defendant is without knowledge or information sufficient to form a belief as to the truth of the averments related to FDA conduct and processes.

44. Defendant specially excepts to the allegations of this paragraph for the reason that they are too vague and ambiguous to allow Defendant to admit or deny same. Subject to and without waiving this objection, Defendant denies that it had notice of any information relevant to the claims set forth herein.

45. Defendant denies the allegations set forth in this paragraph.

46. Defendant denies the allegations set forth in this paragraph.

47. Defendant denies the allegations set forth in this paragraph.

48. Defendant denies the allegations set forth in this paragraph.

49. Defendant denies the allegations set forth in this paragraph.

50. Defendant denies the allegations set forth in this paragraph.
51. Defendant denies the allegations set forth in this paragraph.
52. Defendant denies the allegations set forth in this paragraph.
53. Defendant denies the allegations set forth in this paragraph.
54. Defendant denies the allegations set forth in this paragraph.
55. Defendant denies the allegations set forth in this paragraph.
56. Defendant denies the allegations set forth in this paragraph.
57. Defendant denies the allegations set forth in this paragraph.
58. Defendant denies the allegations set forth in this paragraph.
59. Defendant also incorporates its responses to the incorporated paragraphs.
60. Defendant denies the allegations set forth in this paragraph.
61. Defendant denies the allegations set forth in this paragraph.
62. Defendant denies the allegations set forth in this paragraph.
63. Defendant denies the allegations set forth in this paragraph.
64. Defendant denies the allegations set forth in this paragraph.
65. Defendant denies the allegations set forth in this paragraph.
66. Defendant denies the allegations set forth in this paragraph.
67. Defendant also incorporates its responses to the incorporated paragraphs.
68. Defendant denies the allegations set forth in this paragraph.
69. Defendant denies the allegations set forth in this paragraph.
70. Defendant denies the allegations set forth in this paragraph.
71. Defendant denies the allegations set forth in this paragraph.
72. Defendant denies the allegations set forth in this paragraph.

- 73. Defendant denies the allegations set forth in this paragraph.
- 74. Defendant denies the allegations set forth in this paragraph.
- 75. Defendant denies the allegations set forth in this paragraph.
- 76. Defendant denies the allegations set forth in this paragraph.
- 77. Defendant also incorporates its responses to the incorporated paragraphs.
- 78. Defendant denies the allegations set forth in this paragraph.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that one or more of the following defenses and affirmative defenses will be available to Defendant. Defendant thus gives notice it intends to rely upon any other defense or defenses that may become available including, without limitation, defenses related to the statute(s) of limitations and repose, standing, waiver, estoppel, and laches. Defendant further reserves the right to amend its Answer to assert any additional defenses, whether specifically identified herein or otherwise, as further information becomes available.

Defendant only undertakes the burden of proof as to those defenses deemed affirmative defenses by law regardless of how such defenses are denominated herein. Subject to the foregoing, and without assuming any burden it would not otherwise bear, Defendant asserts the following defenses to preserve its rights:

FIRST DEFENSE:

The Amended Complaint and each cause of action contained therein fail to state a claim upon which relief can be granted.

SECOND DEFENSE:

The Amended Complaint and each and every cause of action asserted therein is, as a matter of law, preempted in whole or in part by federal law, pursuant to *Mutual Pharmaceuticals. Co. v. Bartlett*, 133 S. Ct. 2466 (2013), and *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

THIRD DEFENSE:

Plaintiffs' claims may be preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution because of the pervasive federal regulation of prescription medications, including but not limited to 21 C.F.R. Sections 208.24 (b), (e), 208.3.

FOURTH DEFENSE:

Plaintiffs' claims may be preempted, in whole or in part, by the deference the common law gives in discretionary actions by the Food and Drug Administration under the Food, DRUG and Cosmetic Act.

FIFTH DEFENSE:

Plaintiffs' causes of action are barred, in whole or in part, to the extent discovery or investigation reveals that Plaintiffs' outcome was caused by intervening or superseding events, factors, occurrences or conditions, which were in no way caused by the Defendant and for which the Defendant cannot be held liable.

SIXTH DEFENSE:

Plaintiffs' causes of action are barred, in whole or in part, to the extent discovery or investigation reveals that Plaintiffs' outcome was caused by misuses, abuse, modification, alteration, acts or omissions of Plaintiffs or third parties over whom the Defendant had no control

or authority, including but not limited to Plaintiff's sole or contributory negligence and/or failure to mitigate any alleged injury or damages and, thus, any recovery should be reduced or barred by such parties' proportionate fault.

SEVENTH DEFENSE:

The alleged injuries and damages of which Plaintiffs complain were not caused by any amiodarone product manufactured, sold, or distributed by Defendant, but were caused by some other product, process, occurrence, event, or service over which Defendant exercised no control or right of control.

EIGHTH AFFIRMATIVE DEFENSE:

Any dangers associated with the use of the Defendant's amiodarone product, if any, were not obvious and obvious, and Defendant provided adequate and proper warnings as allowed by law, thus, Plaintiff is barred from recovery.

NINTH DEFENSE:

Defendant is entitled to a credit or offset to any potential verdict/judgment, in the highly unlikely event one were to be awarded in Plaintiff's favor, to the extent that Plaintiffs have released, settled, entered into an accord and satisfaction, or otherwise compromised any causes of action.

TENTH DEFENSE:

Plaintiffs' causes of action are, or may be, barred by the applicable statute of limitations, or statute of repose and/or by the equitable doctrines of waiver, estoppel and/or laches.

ELEVENTH DEFENSE:

Defendant pleads that it is liable only for damages found by the trier of fact equal to their percentage of responsibility, if any. Plaintiffs may not recover damages if their percentage of responsibility is greater than 50% pursuant to Tex. Civ. Prac. & Rem. Code §33.001.

TWELFTH DEFENSE:

Defendant further asserts that Plaintiffs' claims for judgment together with applicable interest are limited by the dates and amounts set forth in the following:

- Art. 5069-1.05 § 6, Tex. R. Civ. Stat.;
- Chapter 304, Texas Finance Code; and
- Chapter 41, Tex. Civ. Prac. & Rem. Code.

THIRTEENTH DEFENSE:

Defendant further asserts that any recovery by Plaintiffs for medical or health care expenses should be limited to the amount actually paid or incurred. Tex. Civ. Prac. & Rem. Code §41.0105. Specifically, Plaintiffs are not entitled to an award of damages for medical bills for which an obligation to pay never existed or has been extinguished through application of contractual credits, offsets or write-offs.

FOURTEENTH DEFENSE:

Defendant expressly invokes the procedural provisions authorized by Texas Civil Practice & Remedies Code Chapter 42.

FIFTEENTH DEFENSE:

Plaintiffs' claims are or may be barred, in whole or in part, by the learned intermediary doctrine. Upon information and belief, Plaintiff was at all relevant times under the care and treatment of licensed physicians who prescribed the medication at issue. If Mr. Villarreal was

injured by the medication manufactured by Defendant, which Defendant denies, Defendant fully informed and disclosed to any physician(s) caring for said patient all relevant information necessary to warn Plaintiffs of any risks associated with using the product. The physicians caring for Mr. Villarreal had a duty to warn him of the risks associated with using any medication at issue. As such, Plaintiffs' claims are barred in whole or in part, by the learned intermediary doctrine.

JURY DEMAND

Defendant also requests a trial by jury and hereby tenders its jury fee.

WHEREFORE PREMISES CONSIDERED, Taro Pharmaceuticals respectfully prays that Plaintiff take nothing by her cause of action, that it recover its costs incurred herein, and for such other and further relief, both at law and in equity, to which it may show itself justly entitled.

/s/ Clark Aspy

Clark Aspy

Texas Bar No. 01394170

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Counsel for Taro Pharmaceuticals USA, Inc.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(b)(1) on the ____ day of October, 2017. Any party who has not yet consented to electronic service is being served by first class mail.

A handwritten signature in black ink, appearing to read "Clark Aspy", is written over a horizontal line.

Clark Aspy